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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,192	09/25/2006	Mette Gronborg	50721/006002	5685

21559 7590 03/29/2011

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1649	

NOTIFICATION DATE	DELIVERY MODE
03/29/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,192	GRONBORG ET AL.	
	Examiner	Art Unit	
	ROBERT C. HAYES	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92 and 129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92 and 129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/5/10;2/18/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/11 has been entered.

2. The rejection of claim 131 under 35 U.S.C. 102(b) as being anticipated by Tang et al/ HYSEQ, INC (WO 01/57190; IDS Ref # B6) is withdrawn due to the cancellation of this claim.

3. Applicant's arguments filed 12/20/10 and 2/18/11 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 92 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 20090618 and 20101001, and as follows. **This is a written description rejection**.

Applicants argue on pages 3-4 of the response their interpretation of the findings of the courts in Fiers and Univ. of California. In contrast to Applicants' arguments, the issue remains that the claims are directed to "treating Huntington's disease…" with variant proteins (i.e., at least 95% identity) of SEQ ID NO: 4, in which only cysteine residues are recited as critical, versus those critical amino acid residues required for "treating" Huntington's disease. As previously made of record, one skilled in the art cannot reasonably visualize or predict what critical amino acid residues would structurally characterize the genus of polypeptides required to be used in the claimed method, as encompassed by claim 92 (i.e., as it relates to "at least 95% identity"), wherein only cysteine residues putatively involved in stabilizing the 3-dimensional structure of any protein are defined. In contrast, no other polypeptides with any functionally definable characteristics are described. Thus, as previously made of record, the specification fails to describe a single critical amino acid residue required for any definable function in the claimed genus; analogous to the situation decided in Fiers v. Revel, and Univ. California v. Eli Lilly and Co., wherein the current claims merely constitute an invitation for others to discover a representative number of species, in order to reasonably extrapolate to the claimed genus, with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, which has not been provided within the instant specification. Thus, Applicants are clearly not in possession of using the claimed genus of NsG33 polypeptides required to practice the currently claimed method, and for the reasons previously made of record. See again MPEP 2163.

6. Claims 92 & 129 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a definable population of neurons affected in Huntington's disease with a structurally and functionally definable NsG33 polypeptide with recited functional characteristics, does not reasonably provide enablement for treating unknown function limitations in unknown neuronal populations in patients with Huntington's disease using structurally and functionally undefined NsG33 polypeptides (i.e., as it relates to "at least 95% identity…"), or biologically functional equivalents thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper NOs: 20090618 and 20101001, and as follows.

Applicants argue on pages 4-7 of the response that "[t]he Office further states that Applicants' data is restricted to one population of neuronal cells in the putatmen (sic)…", and cites teachings from Mizuno et al (1994), Ventimiglia et al (1995), Anderson et al (1996) and Jorgensen et al (2010). In contrast to Applicants mischaracterization of the pending rejection, which alternatively is whether one skilled in the art would known "how to make and use" the instant invention as currently claimed/recited, affecting a known population of neurons using a known and distinguishable assay and a structurally definable protein would define what, at a minimum, the skilled artisan would need to accomplish, in order to enable the invention. In contrast, "treating" Huntington's disease encompasses curing this inherited disease, which neither Applicants nor the art reasonably recognizes. In other words, without minimally increasing survival of striatal/ GABA-ergic medium spiny neurons of the caudate putamen in Huntington's patients (e.g., see pgs. 41 & 98 of the specification, which are also the population

of neurons assayed by Mizuno et al, Ventimiglia et al, Anderson et al and Jorgensen et al), which the current claims fail to recite, no treatment in even the broadest sense is possible, or reasonably assayable/enabled (i.e., knowing "how to use"). Taken a different way, Applicant's arguments regarding certain features of their invention are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification (or from Mizuno et al, Ventimiglia et al, Anderson et al and Jorgensen et al) are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Claims 92 & 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al/ HYSEQ, INC (WO 01/57190; IDS Ref # B6), and for the reasons made of record in Paper No: 20090618.

Tang et al teach administering the polypeptide of SEQ ID NO: 1401, which is 100% identical to SEQ ID NO: 4 of the instant invention (e.g., see pgs 4-5, 28-29 & 65-66), to treat nervous system disorders (section 4.10.17; pgs. 60-61), in which page 61 (line 3) specifically lists treating Huntington's chorea (i.e., as it relates to claim 92 & 94); thereby, anticipating all claims.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert C. Hayes/, Ph.D.
Primary Examiner, Art Unit 1649
March 18, 2011